

## EU Mandate for Conformity Assessment Standards

In the last issues of DAR-aktuell we repeatedly reported about the revision of the New Approach. In February 2007, the EU Commission passed a package of measures consisting of a proposal for a Regulation of the European Parliament and of the Council setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and a proposal for a Decision of the European Parliament and of the Council on a Common Framework for the Marketing of Products.

A text is now available for an EU Regulation and the decision to revise the New Approach, the so-called „Goods Package“, adopted by the European Parliament in its first reading. These documents are expected to be passed by the European Council still in 2008. They can be retrieved from the EU homepage at the following link [http://ec.europa.eu/enterprise/newapproach/review\\_en.htm](http://ec.europa.eu/enterprise/newapproach/review_en.htm)

European standards are required for implementing these legal provisions covering accreditation, conformity assessment and quality assurance. The European Commission therefore mandated CEN/CENELEC and EFTI to harmonize at European level all international standards of conformity assessment required to implement these legal provisions and to publish them in the Official Journal.

For many years the German Institute for Standardization (DIN) and the German representatives in the European committees/boards have recognized the necessity of mandating the conformity assessment standards. This will validate the presumption of conformity when these harmonized standards are applied in the mandatory area. This would mark an essential step in harmonizing the general requirements for conformity assessment bodies, regardless of whether they operate within the frame of EU Directives or in the mandatory area.

Amongst other tasks, the EU Commission mandated CEN/CENELEC and EFTI to identify all ISO/IEC and ITU standards for their relevance with the above New Approach papers, and to present all identified international standards and standards documents which shall be published as harmonized standards. The submitted list of proposed standards contains the following ones:

ISO/IEC 17011:2007 – Conformity assessment; General requirements for bodies accrediting conformity assessment bodies.

ISO/IEC 17020:2004 – General criteria for the operation of various types of bodies performing inspection.

ISO/IEC 17024:2003 – Conformity assessment; General requirements for bodies operating certification of persons.

ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.

ISO 9000:2005 – Quality management systems; Fundamentals and vocabulary.

ISO/IEC 9001:2000 – Quality management systems – Requirements.

ISO 17000:2004 – Conformity assessment; Vocabulary and general principles.

ISO/IEC 17040:2005 – General requirements for peer assessment for conformity assessment bodies.

ISO/IEC 17050-1 and -2:2004 – Conformity assessment of suppliers; Part 1 General requirements; Part 2 Supporting documentation.

ISO 14001:2004 – Environmental management systems; Requirements with guidance for use.

ISO 14004:2004 – Environmental management systems; General guidelines on principles, systems and support techniques.

ISO 14050:2002 – Environmental management systems; Vocabulary.

ISO 14064-1,-2,-3:2006 – Greenhouse gases.

Furthermore there are plans to include standards projects in the mandate. Among others, this applies to the future ISO/IEC 17065—General requirements for bodies operating product certification systems, the future ISO/IEC 17043—Conformity assessment—General requirements for proficiency testing (revision of ISO Guide 43) and to the future ISO 14005—Environmental management systems; Guidelines for a step-by-step implementation of an environmental management system including the use of environmental performance evaluation. The respective standards institutions have to check, amend or change these proposals now.

With this mandate the basis was provided to make the general requirements for conformity assessment bodies and their accreditation in Europe more comparable. When applying these standards, the principle of presumption of conformity is applied, e.g. for conformity assessment bodies operating on the basis of the mandated standards it is to be presumed that they fulfil the requirements of the relevant European Directives.

BAM S.2—M. Wloka

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- ♦ *Merge of DATech into TGA*
- ♦ *Results from DAP and GAZ Evaluations*
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- ♦ *Industry Day in Bonn*
- ♦ *IAJapan Visit at the DAR Secretariat*
- ♦ *EURACHEM/ Eurolab Workshop*

# News from the DAR

## Information from DAR Accreditation Bodies

### 1. Merge of DATech GmbH into TGA GmbH

On 29th September 2007 DATech GmbH (German Accreditation Body for Technology) merged into TGA GmbH (German Association for Accreditation) backdated to 1st January 2007. The TGA GmbH is the legal entity which represents the former accreditation body DATech GmbH legally in the future.

The personnel, the processes and the scope of DATech as far as laboratories, inspection and product certification bodies concerned (former DATech) remain unchanged as well as contact and address data.

Managing director and head of the merged accreditation body is Dr. Facklam, who used to be the managing director both of DATech GmbH and TGA GmbH.

Mr. Ralf Egner and Mrs. Stefanie Friedrich jointly assume the deputy functions of the head of the accreditation body TGA GmbH. Furthermore, Mr. Egner represents the head of the field "Laboratories and Products" (former DATech). Mrs. Friedrich represents the head of the field "Systems and Persons". Both may fill in for one another.

TGA GmbH operating in the fields of laboratories, inspection and product certifica-

tion bodies (former DATech) as well as management systems and persons certification bodies (previous programs operated by TGA) remains a member of the German Accreditation Council.

### 2. GAZ GmbH

The GAZ GmbH informed on its homepage that it ceased to provide its certification activities as of 31st December 2007. The existing certificates will expire on 31st December 2008.

### Status of Evaluation of DAR Accreditation Bodies

**DAP GmbH** The DAP GmbH has been successfully evaluated for the accreditation of certification bodies for management systems according to ISO/IEC 17021:2006 and is allowed to issuing DAR certificates for this program.

One could think that in light of the European developments (see article on page 1) such an extension of the scope would be unnecessary, as in future there will be only one national accreditation body and a merger of the accreditation bodies in Germany operating under the umbrella of the DAR should rather be prepared. However, this scope extension enables the DAP

GmbH already at this stage to offer accreditation under one roof to those customers who operate both certifications of products and management systems.

**GAZ GmbH** The GAZ GmbH successfully finished its evaluation by the BAM Evaluation Committee on 31st October 2007. The GAZ GmbH is entitled to use the DAR certificate for the accreditation of laboratories according to ISO/IEC 17025, of certification bodies for persons according to ISO/IEC 17024, of certification bodies for products according to EN 45011, and of certification bodies for management systems according to ISO/IEC 17021. The GAZ GmbH continues to remain a member of the DAR.

### New DAR Managing Director

In our last issue of DAR-aktuell we informed about the change of responsibilities in the management of the DAR. Dr. Monika Wloka has become the new DAR Chair. Another change of responsibilities took place in the management of the DAR Secretariat. Dr. Gabriele Dudek, known by her activities in supporting the DAR Committee for Technical Issues (ATF), now assumes this function.

*BAM S.2 – S. Stobbe*

### Information System DAR

According to its Rules and Procedures, the DAR Secretariat has the task to be the central contact body for issues dealing with accreditation in Germany. In close cooperation with the accreditation bodies we try to respond on each request as soon as possible. If the request concerns fields beyond our Secretariat's sphere of competence we forward it to the relevant person or body with the request to provide assistance.

The requests are of different nature and often require a comprehensive analysis to determine the category of issue. Such an analysis is followed by the decision on whether the request can be answered by using information from the DAR system or whether further investigations

would be necessary to enable a satisfying reply focused on the main point of the issue.

Sometimes the requests concern only simple provision of information, such as

„Where and how can „I“ be accredited and Who can perform the accreditation?“ or

„Where can I find an accredited body being able to fulfil my needs?“ or

„Would an accreditation actually be required or sufficient ?“

On the other hand, over the years we receive more and more requests requiring comprehensive investigations of the issue, e.g. if requirements for the recognition of accreditations in Germany, Europe and worldwide are concerned and the import/

export of certain products depend on these requirements. Often relevant legal instruments or contact persons need to be ascertained.

If required, our replies are supplemented by selected and publicly available legal provisions, documents, notes and explanations, database excerpts, standards, etc. For requests in English language we provide this supplementary information in English language, if possible. Sometimes we receive requests in other languages which are dealt with as far as the DAR Secretariat or the BAM is able to provide knowledge.

On average about 500 written requests are yearly received by and dealt with at the DAR Secretariat.

*BAM S.2 – N. Bendix*

## News from Standardization

### 23rd ISO/CASCO Plenary Meeting

From 8th to 9th November 2007 the 23rd ISO/CASCO General Assembly took place in Geneva, for the first time chaired by the new ISO/CASCO Chairman Olivier Perrat (AFNOR, France).

#### – Re-organization

Decisions were particularly taken on CASCO's re-organization. The most important change concerns the merger of the Regulator Interface Group (RIG) and the Market Feedback Panel (MFP) into a new Strategic Alliance and Regulatory Group (STAR). It is planned to more and more in-

volve the industry and the authorities in the work of this Group. Time will tell whether in this Group in particular representatives from the authorities will find a listening ear at ISO/CASCO. This is a request of the German Institute for Standardization (DIN) to ISO/CASCO in view of the significance of the conformity assessment standards for the authorities and for a uniform approach both of the authorities and of the industrial sectors in the field of conformity assessment.

#### – Liaison Policy

ISO/CASCO will change its Liaison Policy and adapt it to the ISO policy. Until now

CASCO was excluding regional organizations from the A-Liaison Status and put higher demands on the A-Liaison than ISO. ISO's Policy used to be less strict.

It was decided to enable regional organizations in future to reach the A-Liaison status CASCO, as long as no international organization exists in that particular field.

CEOC (International Confederation of Inspection and Certification Organization) was accepted. So far the European Commission did not apply for the A-Liaison status, but expressed its interest in a closer cooperation with CASCO.

*To be continued p. 3*

## – Market Surveillance

The necessity of standards in the field of market surveillance was discussed at the ISCO/CASCO Plenary Meeting. A respective New Work Item Proposal is not yet scheduled. However, such standards activities are supported by ISO COPOLCO (ISO Committee on Consumer Policy) and ISO DECSO (ISO Committee on Developing Country Matters).

A few members including the German Institute for Standardization (DIN) and ANSI (USA) opposed to the proposal of standards in the field of market surveillance since the authorities may query the acceptance of possible guidelines.

## • Revision of ISO/IEC Directives

Several Chapters of Part 2 of the ISO/IEC Directives deal with the topic of conformity assessment, particularly Chapter 6.7. Demands exist not to include any provisions on conformity assessment (except for testing procedures) in technical standards and to leave it to the authorities or to the respective industrial sectors how to confirm conformity of products or services.

The ISO-CASCO Secretariat put forward a proposed amendment for discussion which would lead to a clear softening of the current policy. This contradicts the Memorandum on conformity assessment requirements set out in standards passed by DIN KONRAT as well as the presidential decision taken by the German Institute for Standardization (DIN). The DIN acts on

the assumption that the provisions on the requirements for conformity assessment lie in the responsibility of the legislator or with the contractual arrangement. When including such provisions in standards their worldwide recognition would be put at risk, as the standards could contradict national requirements. The DIN will therefore decide against this revision. The proposed amendment is still under discussion.

## • Status of Revision of Standards

### Periodic Review

The period of first-time revision of standards was reduced from previously 5 to now 3 years by the ISO General Secretariat, which was criticized by the ISO-CASCO members. More time for utilization and application of the standards on conformity assessment is needed before a revision seems to be reasonable. Therefore the ISO-CASCO Chair will take action against this practice of revision.

### WG 21 – Certification of Management Systems, ISO/IEC 17021

Part 2 *Requirements for auditing management systems by Third Parties* is currently being drafted. The preparation of Part 2 goes along with the revision of ISO 19011—*Guidelines on quality and/or environmental management systems auditing*. Both Working Groups shall closely coordinate their work which is also a requirement of the DIN. A joint committee will be established at the

DIN between the standards committees concerned for revising ISO 19011.

### WG 23 – Common Elements

The Final Draft of PAS 17005 *Conformity assessment—Use of management systems in conformity assessment—Principles and requirements* was rejected by the members, as this Draft did not consider the particularities regarding the quality management system for conformity assessment bodies. A further ISO/CASCO Working Group meeting took place and a new Draft is expected to be prepared.

### WG 28 – Proficiency Testing

The ISO/CASCO Working Group WG 28 is intensively working on the revision of ISO Guide 43 Part 1 and 2—*Proficiency testing by interlaboratory comparisons*. The first Committee Draft is in preparation and will certainly be finished in the first quarter of 2008. The largest discrepancies are to be found in the field of traceability and statement of uncertainty of measurement and handling of subcontracting.

### WG 29 – Product Certification

ISO/IEC Guide 65—*General requirements for bodies operating product certification systems* is currently under revision and shall become a standard ISO/IEC 17065 in the future. Scope, structure and individual contents are still in preparation.

BAM S.2—M. Wloka

## Visit of IAJapan Representatives at the DAR Secretariat

On 10th March 2008, the IAJapan representatives Dr. Katuo Seta, Chief Executive, and Dr. Takashi Arai visited the DAR Secretariat.

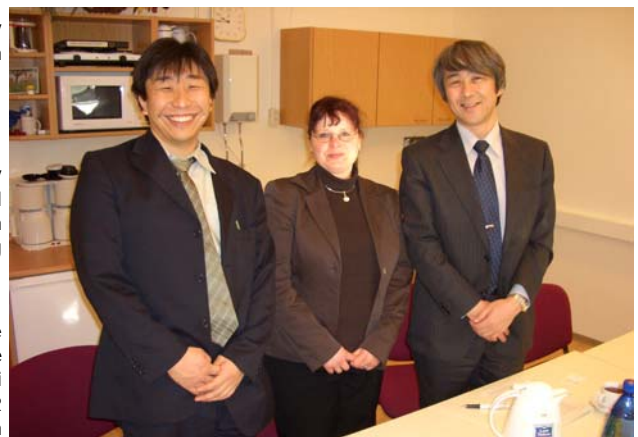
They informed that the Japan Accreditation Council (JAC) has been working in Japan since 2006, but executes more information tasks than the DAR with its coordination activities. In Japan six accreditation bodies are part of different ministries (e.g. Building Trade, Transport, Agriculture). The JAC Secretariat is located at IAJapan. The Ministry of Building Trade and the Ministry of Transport primarily apply national standards, the Ministry of Agriculture has implemented international standards, however without referring to accreditation.

The guests were informed about the

conditions in Germany; they also visited the German Accreditation Body for Technology (DATech) in Frankfurt/Main and gained information about the cooperation between the mandatory and the voluntary areas and the new developments in Germany in view of drafting a German law on accreditation.

In his capacity as the national coordinator of the COMAR Database, Dr. Arai also visited the COMAR Secretariat at BAM in Berlin-Adlershof.

S.2—Dr. J. Thiele



DAR Managing Director Dr. Dudek with the Japanese guests Dr. Katuo Seta (right) and Dr. Takashi Arai (left)

## Third IAF Industry Day in Bonn

On 05th March 2008 the Third Industry Day took place in the La Redoute in Bonn. The First Industry Day was held in San Francisco in 2007 and the Second Industry Day in Beijing in June 2007.

The aim of all these Industry Days was to discuss IAF's strategic aims and tasks with the stakeholders and other parties concerned, and to gather information on

the stakeholders' expectations of IAF.

The IAF Strategic Plan was discussed and the expectations of the stakeholders represented.

In particular, the lecture by Jacques MacMillan, European Commission, presenting the point of view of the regulators with respect to accreditation was awaited anx-

iously. He introduced the European accreditation policy and the new anticipated legal regulations.

The positions of small and medium enterprises as well as the requirements of the industry in different industrial branches were introduced.

To be continued p. 4

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### DIARY:

#### Next EA GAs:

- 04 April 2008, Warsaw (Extraordinary EA GA)
- 28-29 May 2008, Tallinn
- 18-19 November 2008, Portugal
- Spring 2009, Luxembourg
- Autumn 2009, Belgium

#### Next EA MAC Meetings:

- 02-03 April 2008, Warsaw
- 01-02 October 2008, Bucharest

#### Next ILAC/IAF GAs:

- 10-22 October 2008  
Stockholm, Sweden

#### Miscellaneous:

- 08 April 2008 EA Marketing Workshop, BAM Berlin
- 15-16 April 2008 Symposium New developments in measurement uncertainty in chemical analysis
- 12-15 November 2008 International Measurement Confederation - IMEKO TC 11 „Metrological Infrastructure; International Symposium „Metrology, Testing and Accreditation—breaking the trading barriers“, Cavtat, Dubrovnik, Croatia (www.rmo2008.org)

As a result of this Industry Day in Bonn a so-called End-User-Group will be established which will bring together and coordinate the requirements of the stakeholders of IAF and of accreditation and which will make sure that these expectations will be implemented in IAF.

S.2—Dr. M. Wloka

## PLG Workshop 2007 „Accreditation – a tool to develop competence (?)“

On 20th September 2007 a Workshop jointly organized by EA, EUROLAB and EURACHEM on the topic „Accreditation – a tool to develop competence (?)“ took place at the Federal Institute for Materials Research and Testing (BAM), Berlin. EUROLAB-Deutschland arranged for all organizational matters.

106 participants from 27 countries discussed two thematic complexes: firstly, the European development in the field of accreditation and possible consequences for Germany, and secondly, which added benefit would arise for the laboratories from accreditation.



Well-known speakers could be attracted, such as Jacques McMillan from the European Commission, Lorenzo Thione, Chair of EA, or Guy Jacques, the Vice President of EUROLAB aisbl. The lectures can be retrieved from the homepage of EUROLAB aisbl. Eurachem and EA have placed links to the lectures on their websites.

In the panel discussion, issues were particularly addressed regarding cross-frontier accreditation, the future of smaller national accreditation bodies, a control mechanism for the accreditation process as well as for accreditation of notified bodies.

During the workshop discussion on the future structure of the German accreditation system took also place. The discussion was opened by introductory statements given by Professor Ziegler for the voluntary (private) and Mr. Huber for the mandatory (legally regulated) area. While Professor Ziegler addressed the issue of possibilities for merging the accreditation bodies, Mr. Huber emphasized on the differences between both areas. He rather argued for a continuation of both areas, which should, however, merge eventually.

In the discussion it was proposed that competence should by all means be assessed by the accreditation bodies; based on accreditation, in the mandatory area the authorities additionally grant the notification or the national official approval. However, this also caused contrary views. One objection was for example that in this second step the bodies concerned may have to undergo long laborious administrative procedures.

With one consent it was emphasized that existing accreditations and their international recognitions must in no case be questioned. Agreement existed on the fact that the current cooperation of the accreditation bodies in the so-called Nucleus goes quite smoothly and satisfactorily.

During both panel discussions, resolutions were passed which can also be retrieved from the homepage.

In the course of the workshop the opportunity was taken to bid farewell to the long standing Chairman of the DAR, Professor Mittmann who retired from his activities at international level.

EuroLab-D—R. Nüsser

## Symposium - New developments in measurement uncertainty in chemical analysis

From 15th to 16th April 2008 a Symposium will be held at BAM, jointly organized by Eurachem, CITAC and EuroLab. Topics will particularly be the estimation of uncertainty of measurement in sampling as well as in complying of limits. With reference to the guidance documents Eurachem/CITAC Guide „Measurement uncertainty arising from sampling“ and Eurachem/CITAC Guide „Use of uncertainty information in compliance assessment“ different aspects of how to approach uncertainty will be discussed and practical support will be given based on case studies. Further information can be obtained at [www.eurachem.org](http://www.eurachem.org)

Registrations to attend this Symposium can be made at: Roswitha Nüsser, EUROLAB-Deutschland, Unter den Eichen 87, 12205 Berlin, TEL +49-30-8104 3703 / FAX +49-30-8104 3717, [eurolab@bam.de](mailto:eurolab@bam.de)